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October 9, 2024

VIA EMAIL

Erica T. Vest
U.S. Probation Officer
Eastern District of New York
7 Johnson Street
Brooklyn, NY 11201
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Re: *United States v. John Yiu*, 1:23CR00089-001(HG)
Defendant Reply to Government Response to Defense PSR Objection

Dear Officer Vest:

The defense has received the government's October 8, 2024 Response to our August 19, 2024 PSR Objection. We reply now to address government errors in that Response. We will file this Reply with the Court as well.

The government asserts Dr. Yiu prescribed no diclofenac epolamine patches before June 2019. It compares the number of times he prescribed the patch between June and July 2019 (19 times, or 10 times a month) to the twenty month conspiracy period (850 times, or 42 times a month). It thus infers the prescriptions during the conspiracy period had to have been medically unnecessary. But the time periods, and therefore the relative means, are dramatically unequal. They do not support a valid comparison. To be a statistically significant comparison, we would need Dr. Yiu's rate of prescribing diclofenac epolamine patches over at least an equally long period of time, not necessarily limited to this pharmacy.¹ We have no such data.

The government eschews the defense statement that the pandemic influenced patch prescriptions. The government states: "between August 2019 and February 2020 the defendant prescribed diclofenac epolamine to AC Pharmacy customers approximately 225 times, or more than a quarter of his total prescriptions as part of the scheme." Again, the government misleads. By their numbers, Dr. Yiu prescribed the patch 37 times a month during what it calls the 6 month "pre-pandemic" conspiracy period, and 52 times a month during the so-called 10 month "pandemic" conspiracy period. That is an increase of about 36%.²

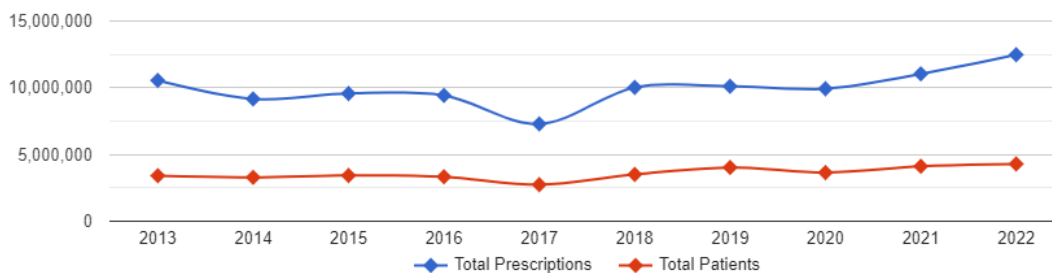
In fact, there was a 25-30% increase in national diclofenac prescriptions during the pandemic, even while the number of patients remained steady.

¹ AC Pharmacy was able to home deliver prescriptions, to clientele who would not otherwise get them during the pandemic.

² Also, many of Dr. Yiu's prescriptions were renewals for the same patient. This, too, tracks the national trend.

Briefly, Diclofenac is a highly effective nonsteroid anti-inflammatory, or NSAID. It is the most widely used NSAID in the world. In 2007, the FDA approved use of the diclofenac patch (it had already had widespread use in Europe).³ From that point on, a host of medical studies evaluated the effectiveness of the patch – dermal application of Diclofenac – over oral and other delivery methods. Consistently, analysts concluded the patch dramatically improved pain management, especially with osteoarthritis. It permitted localized treatment of pain, without the negative issues from systemic distribution throughout the body. With the patch, there were significantly less reports of gastric, cardiac or other negative events. Its use increased orthopedically, post-surgically and elsewhere.⁴ It was of particular importance in treating pain in the elderly.⁵

Prescriptions of it increased. Below is a chart of national Diclofenac prescriptions from 2013-2022.⁶



Between the pandemic years of 2020 to 2022, Diclofenac prescriptions increased 25-30%. This chart does include all forms of Diclofenac. But, given the increased medical recognition of patch advantages, its rate of increase likely exceeded the rate for all other Diclofenac forms. The point is the government's statements do not hold up against the data. The defense statements in its PSR Objection are valid.

The government makes one other significant misstatement. It states the fact that Dr. Yiu expressly denied during his allocution that he wrote medically unnecessary prescriptions "is of no moment." Alas, it is of great "moment." The scope of a defendant's offense conduct is determined primarily by the scope of her allocution. *United States v. Young*, 932 F.2d 1035, 1036-37 (2d Cir. 1991). In *United States v. Goodrich*, 12 F.4th 219, 230 (2d Cir. 2021), the Second Circuit stated: "Where a defendant has pled guilty to an offense, we look to the materials

³ Taguchi T, Yamaguchi S, Terahara T, Okawa K, Inakura H. *Systemically Acting Diclofenac Sodium Patch for Control of Low Back Pain: A Randomized, Double-Blind, Placebo-Controlled Study in Japan*. Pain Ther. 2023 Apr;12(2):529-542.

⁴ E.g., Bhargava GS, Bansal D, Sidhu AS, Bhatia AS. *Diclofenac patch: a better alternative to injectable diclofenac in postoperative pain management*. Int Surg J2015;2:623-8; Taguchi T, Yamaguchi S, Terahara T, Okawa K, Inakura H. *Systemically Acting Diclofenac Sodium Patch for Control of Low Back Pain: A Randomized, Double-Blind, Placebo-Controlled Study in Japan*. Pain Ther. 2023 Apr;12(2):529-542.

⁵ Timothy J. Atkinson, Jeffrey Fudin, Abhinetri Pandula, Maira Mirza, *Medication Pain Management in the Elderly: Unique and Underutilized Analgesic Treatment Options*, Clinical Therapeutics, Vol. 35, # 11, pp 1669-1689 (2013).

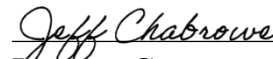
⁶ Kane SP. Diclofenac, ClinCalc DrugStats Database, Version 2024.08. ClinCalc: <https://clincalc.com/DrugStats/Drugs/Diclofenac>. Updated August 7, 2024. Accessed October 8, 2024.

supporting the plea—such as the allocution statement, the plea agreement, and the indictment—to ascertain the ‘offense of conviction.’” (citation omitted). “[W]e will look to the record of the guilty plea proceedings to determine the nature and scope of the ‘offense of conviction.’” Id.

Of course, calculation of the guideline base offense level starts with the offense of conviction. Here, that offense is unlawful receipt of kickbacks, not writing medically unnecessary prescriptions. The latter conduct has neither been alleged nor admitted. It is not a “found fact.” To suggest an upward departure could be based on an unproved fact is wrong. The government backhandedly acknowledges it’s on shaky ground when it states: “at least some of the defendant’s diclofenac epolamine prescriptions lacked medical necessity.” At least some? How many? From when? There is simply no record from which to draw such a weighty conclusion, other than a bare numerical inference. The government states it “makes no request for an upward departure,” but what it gives with one hand it takes with the other. It is wholly inappropriate for the government to misinterpret data while trying to slide ersatz facts in at this stage.

Probation should amend the PSR to grant the defense Objections in full.

Sincerely,



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